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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,081	07/22/2005	Ole Simonsen	10200.204-US	1176

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EXAMINER	
DOUYON, LORNA M	

ART UNIT	PAPER NUMBER
1796	

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08/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,081	SIMONSEN ET AL.	
	Examiner	Art Unit	
	Lorna M. Douyon	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24 and 26-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-24 and 26-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Specification

1. This action is responsive to the amendment filed on May 21, 2008.

2. Claims 18-24, 26-35 are pending. Claims 32-35 are newly added.

3. The objection to the abstract of the disclosure is withdrawn in view of Applicants' amendment.

4. The objection to claim 28 for minor informality is withdrawn in view of Applicants' amendment.

5. The rejection of claim under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicants' arguments.

6. The rejection of claims 18-21, 25-26 and 29 under 35 U.S.C. 103(a) as being unpatentable over DE 2020227 withdrawn in view of Applicants' amendment and arguments therein.

7. The rejection of claims 27-28 under 35 U.S.C. 103(a) as being unpatentable over DE '227 as applied to the above claims, and further in view of Rahman et al. (US Patent No. 6,355,607) withdrawn in view of Applicants' amendment and arguments therein.

8. Claims 18-24, 26, 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa et al. (US Patent No. 5,858,952), hereinafter "Izawa".

Izawa teaches an enzyme-containing granulated product containing, in a uniformly dispersed state, an enzyme and one or more stabilizers selected from the group consisting of reducing agents and antioxidants; a method for the production of the granulated product, as well as bleaching agents and detergent compositions containing the granulated product (see abstract). Examples of stabilizers (which read on the acidic buffer component) include alkali metal salts of boric acid, sodium tetraborate, ascorbic acid, and isopropyl citrate (see col. 2, lines 43-50). The amount of enzymes contained in the granulated product is between 0.01 and 50% by weight (see col. 2, lines 55-62). The amount of stabilizers vary depending on the types of enzymes employed, preferably between 0.1 and 3,000% by weight, more preferably between 1 and 500% by weight, and particularly preferably between 10 and 300% by weight, calculated in relation to the amounts of enzyme protein (see col. 2, line 62 to col. 3, line 1). Powdery bulking agents may also be added if needed, and one example is sodium citrate (see col. 3, lines 42-52). The method for the manufacture of the granulated product includes spray-drying, freeze-drying, extruding, tumbling, fluidized-bed granulation, spray granulation and disintegration granulation (see col. 3, line 63 to col. 4, line 28). The enzyme-containing granulated product preferably has a coating thereon so as to obtain even further improved stability (see col. 4, lines 33-36). Materials used for coating the enzyme-containing granulated product are not particularly limited, and they may include water-soluble film-forming polymers like polyacrylate (see col. 4, lines 33-43). Coating

materials are preferably used in a ratio by weight of 0.1 to 0.7 when the amount of the enzyme-containing granulated product is taken as 1 (see col. 4, lines 47-50). The amount of the enzyme-containing granulated product to be incorporated into a detergent composition is preferably between 0.001 and 70% by weight (see col. 5, lines 6-11). Izawa, however, fails to specifically disclose a core comprising an enzyme and citrate, the amount of stabilizer like citrate in the core, and the pH and pK_a values of the citrate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a core comprising an enzyme and a citrate because Izawa teaches said compounds as suitable stabilizers which are effective in avoiding deactivation of the enzyme and provides a granulated product having excellent solubility as disclosed in col. 1, lines 52-59.

With respect to the amount of stabilizer like citrate in the core, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the portion of the prior art's range (i.e., between 0.1 and 3,000% by weight in relation to the enzyme) which is within the range of applicants' claims because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the prima facie case of obviousness. See *In re Boesch*, 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff* 919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller*, 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). In

addition, a *prima facie* case of obviousness exists because the claimed ranges "overlap or lie inside ranges disclosed by the prior art", see *In re Wertheim,* 541 F.2d 257,191 USPQ 90 (CCPA 1976; *In re Woodruff;* 919 F.2d 1575,16USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2131.03 and MPEP 2144.05I.

With respect to the pH and pK_a values of the citrate salt, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect the citrate salt to possess a pH and pK_a values within those recited because similar components have been utilized.

9. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izawa as applied to the above claims, and further in view of Rahman et al. (US Patent No. 6,355,607), hereinafter "Rahman".

Izawa teaches the features as described above. Izawa, however, fails to disclose the acidic buffer component being NaH_2PO_4 or Na_2H-citrate.

Rahman, in an analogous art, teaches the equivalency of citrate salts with disodium hydrogen citrate and sodium dihydrogen phosphate as acidification components (see col. 2, lines 14-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the citrate salt of Izawa with disodium hydrogen citrate or sodium dihydrogen phosphate because the substitution of art recognized equivalents as shown by Rahman is within the level of ordinary skill in the art.

Response to Arguments

10. Applicants' arguments filed May 21, 2008 have been fully considered but they are not persuasive.

With respect to the obviousness rejection based upon Izawa, Applicants argue that the prior art reference does not show that at least 25% or at least 40% of the core is acidic buffer.

The Examiner respectfully disagrees with the above argument because, as stated above, Izawa teaches in col. 2, line 62 to col. 3, line 1 that the amount of stabilizers (which read on the acidic buffer component) vary depending on the types of enzymes employed, preferably between 0.1 and 3,000% by weight, more preferably between 1 and 500% by weight, and particularly preferably between 10 and 300% by weight, calculated in relation to the amounts of enzyme protein, wherein the amount of enzymes contained in the granulated product is between 0.01 and 50% by weight (see col. 2, lines 55-62). And as stated above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select the portion of the prior art's range (i.e., between 0.1 and 3,000% by weight in relation to the enzyme) which is within the range of applicants' claims because it has been held to be obvious to select a value in a known range by optimization for the best results. As to optimization results, a patent will not be granted based upon the optimization of result effective variables when the optimization is obtained through routine experimentation unless there is a showing of unexpected results which properly rebuts the prima facie case of obviousness. See *In re Boesch*, 627 F.2d 272,276,205 USPQ 215,219 (CCPA 1980). See also *In re Woodruff*

919 F.2d 1575, 1578,16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller,* 220 F.2d 454,456,105 USPQ 233,235 (CCPA 1955). In addition, a *prima facie* case of obviousness exists because the claimed ranges "overlap or lie inside ranges disclosed by the prior art", see *In re Wertheim,* 541 F.2d 257,191 USPQ 90 (CCPA 1976; *In re Woodruff;* 919 F.2d 1575,16USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2131.03 and MPEP 2144.05I.

With respect to the obviousness rejection based upon Izawa in view of Rahman, Applicants argue that claims 27 and 28 depend upon claim 1, and claim 1 is not obvious, hence, these dependent claims are not obvious.

The above response to Izawa applies here as well.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is 571-272-1313. The examiner can normally be reached on Mondays-Fridays 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorna M. Douyon/
Primary Examiner
Art Unit 1796